

SOP Series	SOP 300 Board of Record (BOR)
SOP Title	SOP BOR 302 Coordinated Initial and Ongoing Review Process for Lakeridge Health and Ontario Tech University
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PURPOSE

1. This Standard Operating Procedure (SOP) describes the initial and ongoing review process for research studies involving human participants that have been accepted for ethical review through the Lakeridge Health (LH) and Ontario Tech University Board of Record (BOR) review process.

DEFINITIONS

2. For the purpose of this SOP the following definitions apply:

“Affiliated” means individuals who:

- a. hold academic and/or clinical appointments at the University and/or at LH,
- b. are employed at the University and/or LH, or
- c. Retired University faculty.

“Board of Record” also known as BOR, is the REB of the institution where the main research activities are led. The BOR is responsible for the ethics review, approval, ongoing review, study consultations, monitoring and compliance oversight of the study. The LH institutional senior leadership and/or the University REB Chair decide BOR assignment.

“Delegated Research Ethics Board” also known as DREB, is the REB of the institution that defers the ethics review, approval and ongoing review of the study to the BOR.

“Delegate” is assigned responsibility by the REB Chair for decision-making to provide ethics review support to the University REB.

“Minimal Risk” is defined as research in which the probability and magnitude of possible harm implied by participation in the research is no greater than that encountered by research participants in those aspects of their everyday life that relate to the research.

“REB Administrator” is the Research Ethics Officer at the University or Research Liaison at LH who provides support and liaises with the research community and REB.

“REB” refers to the Research Ethics Board authorized by the University and/or Lakeridge Health.

“Principal Investigator (PI)” is the head of the research team who has overall responsibility for the ethical conduct of the study and for the actions of any member(s) of the research teams. The PI is responsible for communicating any changes to the study, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site researchers for multi-site studies. The PI is responsible for completing the University or LH REB application. The PI must be affiliated with The University and/or LH.

“Research activity(ies)” involve participant enrolment and recruitment, research interventions, data collection and data analysis.

“Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans” referred to as “TCPS2” is the joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This policy outlines ethical norms relevant to the conduct of research involving humans.

“University” means the University of Ontario Institute of Technology (Ontario Tech University).

SCOPE AND AUTHORITY

3. This SOP applies to the University REB Chair (or delegates) and University REB Administrator, or successor thereof, is the Policy Owner and is responsible for overseeing the implementation, administration and interpretation of these Procedures.

PROCEDURES

All research projects involving human participants require Research Ethics Board (REB) approval prior to study initiation. The Board of Record (BOR) review process will streamline ethics review between Lakeridge Health (LH) and the University so that an ethics submission is only required at one institution. Under the LH-University BOR review process, a BOR designation is assigned to either the LH or the University REB. This is a decision that will be mutually agreed upon by each REB. Upon assignment of a BOR, the PI shall submit a REB submission to the assigned BOR. The BOR will carry the responsibility for the initial review, approval and ongoing **ethical review**, monitoring and compliance oversight of the study.

4. Eligibility for BOR review process

- 4.1. To qualify for a BOR review, a project team member (e.g. Principal Investigator or Co-Investigator) must be affiliated with LH and/or the University.
- 4.2. At the discretion of the University REB Chair (or delegate), the University REB reserves the right to conduct an independent research ethics review of **any** research involving humans at any time.

5. New applications submitted to the REB

- 5.1. Researchers are encouraged to consult with their institutional REB when considering research projects involving LH and the University for guidance on the submission process.
- 5.2. For submissions received in the IRIS Research Portal, the University REB Administrator, in consultation with the University REB Chair (or delegate) shall pre-screen all incoming REB applications involving the University and LH for eligibility to undergo a BOR review.
- 5.3. The University REB Chair (or delegate) shall use their judgement and the principles of the TCPS2 to assign the risk level that will inform the review pathway for the studies (e.g. full board review or delegated review).
- 5.4. Applications that meet the eligibility criteria for BOR review, the University REB administrator shall promptly notify LH REB for consideration as a BOR review.

6. **BOR Assignment**

- 6.1. Once a project has been deemed as eligible to undergo a BOR review, each REB will work together to assign a BOR.
- 6.2. The BOR will be assigned to the REB of the institution where the **primary activities** will be led.
- 6.3. The other institution that defers REB review to the BOR, will be considered as the Delegated REB (DREB) and will accept the decisions of the BOR. To illustrate, if the PI's home institution is LH, and the project will involve research activities at the University only, the BOR will be assigned to University since the primary research activities are led at the University. In this case, LH will be assigned as the DREB. As another example, if the LH PI will conduct research activities at both institutions, a mutual decision will be made between the REBs as to which institution will be assigned as the BOR.
- 6.4. When the University is assigned as the BOR, the PI will be notified by the University REB administrator about the BOR assignment and to complete an intake form for submission to LH as the DREB.
- 6.5. When LH is assigned as the BOR, the PI will be notified by the LH REB administrator about the BOR assignment and to complete an intake form for submission to the University as the DREB.

7. **BOR Review Process and Records Management**

- 7.1. The BOR shall be responsible for all aspects of the initial **ethical review**, ongoing review, monitoring and compliance oversight of the applications undergoing a BOR review process. This includes the REB review decision letter, responses to the decision letter, issuing of study decisions and study consultations.
- 7.2. The BOR REB administrator functions as the principle point of contact for the researchers and shall provide administrative support for the BOR coordinated review process.
- 7.3. The BOR REB Administrator will initiate the REB of Record Study Agreement that will be signed by the appropriate institutional representative(s). For example, the institutional representative responsible for signing the Agreement is the President & Vice-Chancellor when Ontario Tech is the BOR.
- 7.4. The application undergoing a BOR review process shall be reviewed and approved according to the designated BOR's established review pathway and will commence once the applicable BOR intake form is completed and when the REB of Record Study Agreement is signed by representatives from the DREB and the BOR.
- 7.5. The PI will be responsible for obtaining any further approvals/permission that might be required to complete the study prior to initiation.
- 7.6. The BOR will communicate all decisions in writing to the PI. The BOR shall manage and retain all documentation surrounding the initial and post review activities.
- 7.7. When Ontario Tech is the DREB, the PI must submit the approved REB application, all approved supporting documentation and REB approval from LH as an *Additional Documentation for REB* post approval event in IRIS for record keeping purposes.

8. **BOR Ongoing Review**

- 8.1. The ongoing review, post approval activities (e.g. change requests and yearly progress reports) monitoring and follow-up reporting of anticipated issues, adverse events and non-compliance will be overseen and managed according to the designated BOR's established SOPs and policies.
- 8.2. When the University is the BOR, ongoing review activities will be managed according to the University's REB SOP 207 Ongoing Review of Approved Research.

MONITORING AND REVIEW

9. These Procedures will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes). The REB Chair and REB Administrator, or successor thereof, is responsible to monitor and review these Procedures.

RELATED POLICIES, PROCEDURES & DOCUMENTS

10. REB SOP 205 (The Full Review Process)
11. REB SOP 207 Ongoing Review of Approved Research
12. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2018)